510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
DEVICE ONLY TEMPLATE

A. 510(k) Number:
K032002

B. Analyte:
Follicle stimulating hormone

C. Type of Test:
Qualitative

D. Applicant:
Genosis, Inc.

E. Proprietary and Established Names:
Fertell Female Fertility Test

F. Regulatory Information:

1. Regulation section:
   21 CFR 862.1300
2. Classification:
   Class I
3. Product Code:
   NGA
4. Panel:
   75

G. Intended Use:

1. Intended use(s):
   The Fertell Female Fertility Test is intended to measure follicle stimulating hormone (FSH) in urine as an adjunctive screen of fertility for home use by women who are attempting to conceive but have been unsuccessful.
2. Indication(s) for use:
   The Fertell Female Fertility Test is intended to measure follicle stimulating hormone (FSH) in urine as an adjunctive screen of fertility for home use by women who are attempting to conceive but have been unsuccessful.
3. Special condition for use statement(s):
   This device is intended for over-the-counter use (OTC).
4. Special instrument Requirements:
   Not applicable

H. Device Description:

The test kit consists of 1 female testing device (foil pouched) and 1 instruction booklet. The test device contains monoclonal anti-human α-subunit of FSH (conjugated to colloidal gold) and monoclonal anti-human FSH (capture antibody). The nitrocellulose strip also has a comparator line of fixed intensity that corresponds to an FSH concentration of 10 IU/L.

The test is performed two days after the onset of menses (day 3 of the menstrual cycle) by urinating directly on the absorbent tip or by dipping it in a cup of urine, and

observing for the formation of colored lines after 30 minutes. A test line of color intensity greater than or equal to the comparator line indicates diminished ovarian reserve.

I. Substantial Equivalence Information:

1. Predicate device name(s):
   Abbott AxSYM FSH
2. Predicate K number(s):
   K935612
3. Comparison with predicate:

Similarities		
Item	**Device**	**Predicate**
Intended Use	Measurement of FSH	Measurement of FSH
Test Principle	Two-site immunometric assay	Two-site immunometric assay
Differences		
Item	**Device**	**Predicate**
Intended Use	Over-the-counter use	Clinical laboratory use
Type of Test	Qualitative	Quantitative
Sample	Urine	Serum or plasma
Label (Detection)	Colloidal gold	Alkaline phosphatase
Support for Capture Antibody	Nitrocellulose strip	Microparticles
Interpolation of Result	Visually compare test line to the reference line	Automated data reduction comparing test signal with stored calibration data
Detection Limit	10 IU/L	0.37 IU/L

J. Standard/Guidance Document Referenced (if applicable):
None Referenced

K. Test Principle:
The test is a lateral flow immunochromatographic assay. FSH in the urine reacts with the conjugated and immobilized antibodies, forming a sandwich.

L. Performance Characteristics (if/when applicable):

1. Analytical performance:
   a. *Precision/Reproducibility:*
   Seven control pools in the range of 2.9 – 20.5 IU/L FSH (IS 92/510) were measured on 20 separate days by the same operator using the same batch of devices. Test reproducibility was 98% based on

consistency of result classification, i.e., 139 out of 142 results were correctly classified.

b. *Linearity/assay reportable range:*
Not applicable

c. *Traceability (controls, calibrators, or method):*
The Fertell Female Fertility Test has been developed with reference to FSH concentrations measured in matched serum samples, collected from subjects within the same working day as the first morning urine specimen. The cut-off for the test has been developed to be equivalent to 10 IU/L serum FSH. The correlation against matched serum FSH 10 IU/L has been used to define whether the calibration of the test is acceptable, and FSH IS 92/510 standards and quality control samples have been used as a reference.

d. *Detection limit:*
Fourteen urine specimens were selected with FSH levels (calibrated against FSH IS 92/510) distributed around the test cut-off. Grouped according to above or below the cut-off, they were in the range of 4.3 – 7.5 IU/L (39% below cut-off to approximately equal to cut-off) and 9.0 – 13.3 IU/L (28 – 90% above cut-off).

Specimens were assessed in singleton, with each of 3 different lots of Fertell Female test devices. All three lots yielded negative results for FSH concentrations between 4.3 – 7.5 IU/L and positive results for FSH concentrations between 9.0 – 13.3 IU/L. The mean nominal FSH level of the seven negative samples assessed was 5.5 IU/L, and the mean nominal FSH level of the seven positive samples assessed was 10.1 IU/L.

e. *Analytical specificity:*
Potential cross-reacting substances (thyroid stimulating hormone [TSH], luteininzing hormone [LH], and human chorionic gonadotropin [hCG]) at elevated physiological concentrations were spiked into five urine specimens containing concentrations below the test cut-off and five specimens above the test cut-off. The results showed no cross-reactivity from TSH at 20 mIU/mL, LH at 100 IU/L, or hCG at 100,000 IU/L.

Elevated concentrations of drugs and chemical analytes were spiked into five urine specimens containing FSH at concentrations below the test cut-off and five specimens above the cut-off. Interference was initially observed for a high level of ascorbic acid and glucose (i.e., two samples with FSH concentrations above the test cut-off read negative). However, retesting found no interference for ascorbic acid at a level above the maximum concentration expected during a saturation test and no interference for glucose at a level 40-fold higher than the upper reference interval for glucose in urine. No interference was observed for the other substances.

Potentially interfering bacteria (representing a gross level of bacterial infection) were spiked into five urine specimens containing FSH at concentrations below the test cut-off and five specimens above the cut-off. No interference was observed for the Gram negative or Gram positive bacteria.

pH was evaluated for interference by testing five urine specimens containing FSH at concentrations below the test cut-off and five specimens above the cut-off with and without adjustments made to the pH. No interference was observed over the pH range of 5.2 – 8.2.

f. Assay cut-off:
See Detection limit above.

2. Comparison studies:
   a. Method comparison with predicate device:
   The objective of this study was to demonstrate equivalence between results from the two test methods. Specimens from various times within the subjects' menstrual cycles were used.

   The data were derived from the same subjects who took part in the lay user versus professional study. A blood sample was collected from the patients and evaluated on the Abbott AxSYM FSH. Any results that were discrepant between the professional and the serum FSH were repeated. Results that agreed after initial discrepancy were classified as equivocal and discarded from the data analysis. One hundred fifty subjects participated in the study, which was performed at one site using three batches of product. Results from seven participants were considered equivocal and were excluded from the analysis.

   The results from the remaining one hundred forty-three (143) subjects showed a percent accuracy against the predicate method of 95.1%.

   b. Matrix comparison:
   Not applicable
3. Clinical studies:
   a. Clinical sensitivity:
   Not applicable
   b. Clinical specificity:
   Not applicable
   c. Other clinical supportive data (when a and b are not applicable):
   Not applicable
4. Clinical cut-off:
   Not applicable
5. Expected values/Reference range:
   The expected value of day 3 urine FSH has been established in the literature.

M. Conclusion:

The intended use of the Fertell Female Fertility Test is similar to several quantitative FSH tests that identify a variety of medical conditions associated with abnormal FSH levels, including an assessment of ovarian reserve. The Fertell Female Fertility Test is technologically similar to several OTC FSH tests. The data provided, including consumer field evaluations and other studies not listed above, were adequate. Day 3 urine FSH testing and its association with ovarian reserve are supported by literature. Additionally, the labeling clarifies that the test is a screen for diminished ovarian reserve and cannot detect all causes of infertility, it cannot be used for contraception or to time when one ovulates, it should not be used in patients undergoing assisted reproductive techniques, and it clarifies when further testing may be appropriate and recommends consulting a physician. Therefore, I recommend a substantial equivalence determination for the Fertell Female Fertility Test.